

Applicants: Geijtenbeek et al.  
Serial No.: 10/533,981

Docket No. 1943-2 PCT/US RCE  
Filed: October 5, 2005

### **Remarks**

In response to the Office Action, Applicants have amended claim 68, cancelled claim 76, added new claim 77, and submit the following remarks. Claims 68-75 and 77 are pending.

### **Support for Amendment to Claim 68**

Claim 68 has been amended to specify that the antigen of interest is covalently attached to at least one non-sialylated Lewis x antigen to form a glycoconjugate. By doing so, the antigen is targeted to a C-type lectin receptor on an antigen presenting cell.

Support for the amendment to claim 68 can be found throughout the specification which discusses at length the characteristics and benefits of utilizing a glycoconjugate. By definition, a glycoconjugate is the general classification for carbohydrates covalently linked with other chemical species.

### **Rejection under §112**

Claim 67 has been rejected under §112, first paragraph, as allegedly lacking enablement. In response, and in the spirit of moving the application towards allowance, Applicants have cancelled claim 67,

Accordingly, the above §112 rejection has been rendered moot.

### **Rejection under §102**

Claims 68-76 have been rejected under §102(b) as allegedly being anticipated by WO 97/27872 ('872). According to the Examiner, '872 teaches a method of stimulating

an antigen specific immune response or a Th2 cytokine response comprising administering an antigen comprising a Lewis x antigen glycoconjugate; and that the method can be used for the treatment of autoimmune disease.

The Examiner goes on to add that '872 teaches that the antigen can comprise a protein that inherently comprises peptides capable of binding to MHC class I or II., and would inherently bind to DC-SIGN, since they comprise the DC-SIGN ligand Lewis antigen x. Applicant respectfully disagrees.

'872 provides methods for modulating an immune response. The methods of '872 involve contacting an immune cell with an agent that modulates interaction of a compound comprising a Lewis antigen with the immune cell such that production by the immune cell of at least one cytokine that regulates development of a T helper type 1 or T helper type 2 response is modulated (See abstract of '872).

It is said in the '872 application that the invention is based on the discovery that stimulation of a variety of cell types with Lewis antigen-containing conjugates results in the production of cytokines that regulate the development of a Th1 or Th2 response.

As such, the '872 application is not concerned with a method of stimulating an immune response directed towards a particular antigen, different from the Lewis antigen. Rather, the '872 application describes a method for modulating an immune response in general.

The '872 method may, however, be applied for stimulating an antigen-specific immune response in that an antigen to which an immune response is to be induced (a non-Lewis antigen) is co-administrated with a Lewis antigen as two separate entities.

This may clearly be derived from several places in the description, for instance on page 4 lines 27 – 30 and page 24 line 10.

Therefore, '872 teaches that a specific immune response to an antigen may be stimulated by administering to a subject: (i) the antigen and (ii) a stimulatory form of an agent comprising a Lewis antigen. It is clear from '872 that the Lewis antigen functions as an adjuvant so that the immune response to the antigen is enhanced.

This greatly differs from the present invention. The present invention now claims a method for stimulating an immune response towards a particular antigen wherein that particular antigen is attached to the Lewis antigen, to form a glycoconjugate. This means that the antigen to which an immune response is sought and the Lewis antigen are covalently attached to each other and are within the same molecular complex, rather than physically mixed.

The present invention is not an obvious modification of the teaching of the '872 application. A skilled person would not have contemplated to covalently attach the antigen to the Lewis antigen, because he was not aware of the affinity for Lewis antigens of DC-SIGN on antigen presenting cells, as taught in the present application.

With the inventor's discovery, the present invention now opens the opportunity to direct antigens more specifically to antigen presenting cells by covalently attaching them to Lewis antigens.

In fact, the '872 application teaches away from the present invention in that a skilled person thinking along the lines as taught in '872 would expect the best results when all epitopes on the antigen are available and not shielded by conjugation to the Lewis antigen.

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It is only with the benefit of the teaching of the present invention that a skilled person would consider to covalently attach an antigen to a Lewis antigen.

In light of the amendments to the claims and the above remarks, it is respectfully submitted that the '872 application does not anticipate the claimed invention.

Reconsideration and withdrawal of the §102 rejection based on '872 is respectfully requested.

It is now believed that this application is in condition for allowance. If the Examiner believes that resolution of any remaining issues can be handled via telephone, she is cordially invited to contact Applicants' Attorney at the telephone number listed below.

Respectfully submitted,

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